Indian Pharmacopoeia Commission
National Coordination Centre (NCC) - Pharmacovigilance Programme of India (PvPI)

PvPI Monthly Progress Report- January 2017

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1	Data collation and processing of ICSRs	During the index period, NCC received 5932 ICSRs from AMCs/ Pharmaceutical industries/ consumers. The reported cases are under assessment for completeness, listed/ unlisted and clinical relevance.	The reported ICSRs yet to be assessed for the completeness & quality for further process (listed and unlisted) & under medical/clinical review. Lack of quality/incomplete reports will be reverted back to the reporter.
2	Collaboration with NABH for Pharmacovigilance Activities	NCC-PvPI, IPC had a meeting with NABH Officials. A Memorandum of Understanding signing ceremony was organised by IPC at CDSCO Headquarter, FDA Bhawan, New Delhi on 10th Jan 2017.	The objective of this MoU between IPC and NABH is to promote monitoring and reporting of Adverse Drug Reactions (ADRs) by NABH accredited hospitals to Pharmacovigilance Programme of India. Indian Pharmacopoeia Commission is the National Coordination Centre for Pharmacovigilance Programme of India.
3	MvPI partners review Meeting	NCC-PvPI, IPC organised MvPI partners review meeting on 9th January 2017 at IPC, Ghaziabad.	The outcome of this meeting as follows: • Members suggested to identify new Medical Device Adverse Event Monitoring Centres (MDMCs), where the Medical Colleges having Bio-Medical engineering department.

			• The committee suggested the following: (a) Two days Induction cum training programme for the Coordinators of the MDMCs should be conducted in the month of February 2017 at IPC, Ghaziabad. (b) Selected Research Associates (Contractual) under MvPI should join MDMCs first and then they may be called for Induction cum training at IPC along with/ after the coordinators training. • The committee suggested to conduct Steering Committee and Working Group meeting at IPC during coordinators training in Feb. 2017. • MvPI-Guidance Document a) The guidance document drafted by NCC-PvPI and NHSRC should be placed before the working group for approval. b) The committee also decided to consider the comments received from CII on MDAE form later as the programme is in its very initial phase and culture of reporting need to be developed. • SOP and other Documents of MvPI The work for the preparation of SOPs and other documents shall be initiated after the recruitment of Research Associates

4	Expert Committee meeting for assessment of PSURs	11th meeting of PSUR-Expert Committee for assessment of PSURs was held on 12th & 13th January at CDSCO, FDA Bhawan, New Delhi	During this meeting experts reviewed the following Vaccine PSURs 1. Typhoid vaccine 2. Meningococcal vaccine 3. Pneumococcal vaccine 4. Rabies vaccine 5. Pentavalent vaccine (Follow up, New Cases) 6. Oral cholera 7. Rota virus vaccine (Follow up, New Cases) 8. Human Papilloma vaccine (Follow up, New Cases) 9. Herpes zoster vaccine

5	Skill Development Programme on Basics and Regulatory Aspects of Pharmacovigilance: Striving for Excellence	PvPI organised Skill Development Programme on Basics and Regulatory Aspects of Pharmacovigilance for the States/UT's of U.P, U.K, Manipur, Chandigarh, and Delhi from 16th to 25th January at IPC, Ghaziabad.	Total 50 participants attended this programme. The programme was inaugurated by DCG (I). The outcome of this skill development programme is as follows: 1. NCC-PvPI to submit a note to DCG(I) office stating that Pharmaceutical companies and other organizations, while appointing a personnel in Pharmacovigilance Unit, a preference must be given to the candidates those have undergone skill development Programme of PvPI that will ensure the Qualified Person for Pharmacovigilance (QPPv) in Pharmacovigilance Cell/Division of the Organization. 2. The staff working in PvPI should be designated as follows: a) Pharmacovigilance Associates to be re-designated as Patient Safety-Pharmacovigilance Associates b) Sr. Pharmacovigilance Associates to be re-designated as Sr. Patient Safety-Pharmacovigilance Associates c) Pharmacovigilance Officer to be re-designated as Patient Safety-

			Pharmacovigilance Officer 3. He appreciated the efforts of PvPI team at NCC and suggested to expand this training module to the Regional Training Centres (RTCs) of PvPI in the year 2018. 4. He urged all the participants to contribute for patient safety/ Pharmacovigilance since health sector is going to be a driving force of Indian Economy.
6	Preliminary meeting for Benefit-Risk assessment	NCC-PvPI, IPC had a preliminary meeting with expert on 31st January 2017 at IPC, Ghaziabad.	The outcome of the meeting is as follows: 1. Reviewed Draft SOP on Benefit-Risk Assessment 2. Reviewed Guidance document chapter on Benefit-

			Risk Assessment
7	Interaction with State/ Central Drug Regulatory Authorities for abating the lack of efficacy drugs/ Preventing the use of spurious drugs	• NCC-PvPI received ICSRs and complaint with regard to Rigors and Chills associated with Metronidazole from Madurai Medical College which was observed in Govt. Rajaji hospital, Madurai • NCC-PvPI received complaints with regard to blood stream infections associated with use of Ultrasound Jelly from KG Hospital, Coimbatore reported from Coimbatore Medical College (AMC) • NCC-PvPI received complaints with regard to therapeutic inefficacy associated with use of Lignocaine HCl from SV Medical College & Hospital (AMC), Tirupathi	• PvPI has assessed the case with help of Adverse Drug Reaction Monitoring Centre (AMC) and based on medical reviewer suggestions it was found that the batch of product may got contaminated which lead to the unexpected reaction. PvPI has informed the same issue with State Drugs Controller of TamilNadu and the use of drug was stopped in the respective region. • PvPI has assessed the case with help of AMC and based on all laboratory investigations and supporting documents it was found that the batch of product got contaminated which lead to the serious reaction. PvPI has informed the same issue with State drug Controller of TamilNadu and the use of product was stopped in the respective region. • PvPI has informed the issue with help of AMC to State Drug Regulatory Authority of Andhra Pradesh for investigation and necessary action.